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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,648	09/24/2001	Robert F. Sak	004122.00006	6515

22907 7590 10/21/2003

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EXAMINER

MCCROSKY, DAVID J

ART UNIT	PAPER NUMBER
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3736

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DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,648

Applicant(s)

SAK, ROBERT F.

Examiner

David J. McCrosky

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The indicated allowability of claims 1-15 and 20-27 is withdrawn in view of the newly discovered reference to Sak. Rejections based on the newly cited reference follow.

Claim Objections

Claim 28 is objected to because of the following informalities: "the fixative" in lines 2 and 3 should read --the ethanol based fixative-- to properly refer to its antecedent. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation "the cervical sampler" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

Art Unit: 3736

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,302,853 to Sak. Although the conflicting claims are not identical, they are not patentably distinct from each other because Sak claims a cervical sampling apparatus comprising a vaginal insertion tube, an introduction guide member and a cervical sampler.

Claims 20-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-30 and 33 of U.S. Patent No. 6,302,853 to Sak in view of Schuster et al. Sak claims a method of obtaining cervical samples comprising inserting an introduction guide member, introducing a vaginal insertion tube, withdrawing the introduction guide member, advancing the vaginal insertion tube, inserting a cervical sampling member and extending a sample collecting member. Sak does not claim applying an ethanol based fixative onto the cervical sampling member after removal. Schuster et al teach applying an ethanol based fixative after removal of the cervical sampling member to prefix the cells. See col. 4, ll. 5-8. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sak with applying an ethanol based fixative, as taught by Schuster et al, to prefix the cells.

Claim 28 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-30 and 33 of U.S. Patent No. 6,302,853 to Sak in view of Schuster et al and Hasselbrack. Sak claims a method of obtaining cervical samples comprising inserting an introduction guide member, introducing a vaginal insertion tube, withdrawing the introduction guide member, advancing the vaginal insertion tube, inserting a cervical sampling member and extending a sample collecting member. Sak does not claim applying an ethanol based fixative onto the cervical sampling member after removal. Schuster et al teach applying an ethanol based fixative after removal of the cervical sampling member to prefix the cells. See col. 4, ll. 5-8. Sak and Schuster et al do not teach spraying the ethanol based fixative. However, Hasselbrack discloses spraying a fixative to preserve the sample. See col. 7. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sak with applying an ethanol based fixative, as taught by Schuster et al, and spraying the fixative, as taught by Hasselbrack, to prefix the cells and to provide an even distribution of the fixative on the sample.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on 703-308-3130. The fax phone

Art Unit: 3736

number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DJM


MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700